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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,119	03/30/2001	June Kaplow	P23,461-A USA	9257

7590 11/17/2003

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,119	Applicant(s) KAPLOW ET AL.	
	Examiner Janet L. Epps-Ford, Ph.D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) 2,4-25 and 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9-09-2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 2, 4-25, and 29-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the Paper filed 8-29-03.
2. Applicant's election with traverse of Group I, claims 1, 3, and 26-28 in the Paper filed 8-29-2003 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct inventions since NFIF-7a and NFIF-14b are related inventions because NFIF-14b is a full-length polypeptide and NFIF-7a is a splice variant thereof. This is not found persuasive because although the two polypeptides may be "related" or even dependent inventions since they are splice variants, absent evidence to the contrary the two polypeptides are nonetheless distinct to the extent that they have distinct sequences and would require a separate search and consideration of the prior art. Furthermore, one of ordinary skill in the art would recognize that the polypeptide amino acid sequence determines the overall tertiary structure of the polypeptide, and the structure of the polypeptide would determine its function. Since the two polypeptides would possess a different structure due to their distinct amino acid sequence, they would also be expected to possess different functions and/or modes of operation. Applicant's arguments do not take the place of evidence that would support Applicant's assertions that the NFIF-14b and the NFIF-7a polypeptides are separate and distinct inventions.

Moreover, according to MPEP § 803, "an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate

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patents and they are *either* independent (MPEP § 806.04 - § 806.04(i)) *or* distinct (MPEP § 806.05 - § 806.05(i)). It is not required that two inventions be both independent and distinct in order for a restriction to be proper, the question is whether or not the two inventions can support separate patents and that they are either independent or distinct. In the instant case, it is clear that the two inventions can support separate patents, are distinct because of the differences in amino acid sequence structure, and the necessity for separate searches and separate considerations of the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Sugano et al. (See IDS, Sheet 2 of 3, reference AF, February 22,2000).

The instant claims are directed to a nucleic acid encoding NFIF-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1), and further wherein said DNA is a cDNA.

Sugano et al. discloses a cDNA molecule of 1760 nucleotides in length. This nucleotide sequence comprises 1361/1362 identical nucleobases (i.e 99% identity) of the nucleotide sequence according to SEQ ID NO: 3 of the instant application. The sequence according to SEQ ID NO: 3 of the instant application is disclosed as encoding the amino acid sequence according

to NFIF-14b (See Figure 3 of the instant application). Absent evidence to the contrary, the cDNA sequence of Sugano et al. encodes the NFIF-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1) of the instant application.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites “[A] nucleic acid encoding NFIF-14b polypeptide comprising an amino acid sequence as shown in Figure 1 (SEQ ID NO: 1).” In the instant case, the claim reads on a product of nature, since the claim does not indicate the hand of man in the isolation of the nucleic acid encoding NFIF-14b polypeptide.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 3 recites the limitation "said DNA" in line 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 26-28 provide for the use of a nucleic acid encoding an NFIF polypeptide, a recombinant vector comprising said nucleic acid, or a defective recombinant viral vector

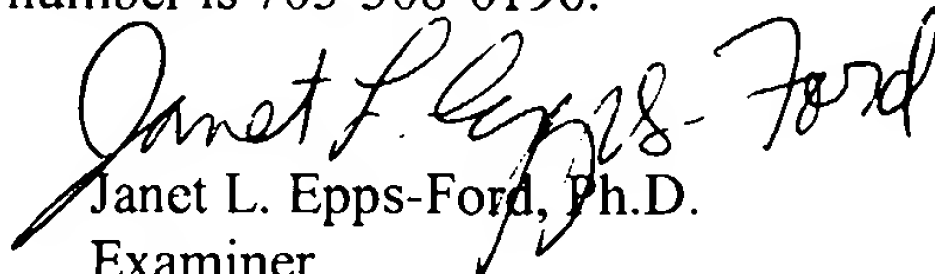
comprising said nucleic acid, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 26-28 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE